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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,735	02/04/2004	Takashi Tokuyama	F-8021	4827
28107 7590 11/28/2007 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168				
			EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/771,735

Applicant(s)

TOKUYAMA ET AL.

Examiner

Randall Winston

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>0804</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of species of 1) ethanolamine 2) 1,3-butylene glycol 3) antiphologistic agents 4) atopic dermatitis 5) atopic skin in the reply filed on 09/10/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Readable Claims 1-26 and 29 will be examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a method of improving moisture retention ability of skin and/or treating or protecting skin comprising ethanolamine, the specification does not enable any person skilled in the art to prepare a method of preventing skin diseases comprising ethanolamine.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the

Art Unit: 1655

art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of preventing skin diseases comprising ethanolamine. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 6-56, examples 1-15, of the specification a method of improving moisture retention ability of skin and/or treating or protecting skin comprising ethanolamine. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a method of preventing skin diseases comprising ethanolamine

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a method of preventing skin diseases comprising ethanolamine.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 25-26 are rejected under 35 USC 102(b) as being anticipated by Tanaka et al. (US 5128375).

Applicant claims a method of treating the skin by applying to the skin a composition comprising ethanolamine.

Tanaka anticipates the claimed invention because Tanaka teaches a method of treating the skin by applying to the skin a composition comprising ethanolamine (see, e.g. entire patent including abstract). Therefore, the reference is deemed to anticipate the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (US 5,753,214) in view of Tanaka et al. (US 5128375) and Pola Chem Ind Inc (Derwent Acc-No 1995-175320 and/or JP 07097312A, see abstract) as evidenced by Pearson et al. (6,951,658).

Applicant claims a method of treating the skin by applying to the skin a composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent).

Yoshioka teaches a composition comprising L-arginine (please note, as evidenced by Pearson et al. L-arginine is inherently found in rice, thus, it is considered a

"rice preparation"), and an antiphlogistic agent (i.e. anti-inflammatory agent) used within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. entire patent including the abstract, column 9 lines 1-35, column 17 lines 23-34).

Yoshioka et al. do not expressly teach ethanolamine and a moisture retention agent of 1,3-butyleneglycol included within its cosmetic composition to be applied to a subject's skin to treat skin disorders.

Tanaka beneficially teaches ethanolamine contained within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. claim 15).

Pola Chem Ind Inc beneficially teaches 1,3-butyleneglycol contained within a cosmetic composition to be applied to a subject's skin to treat skin disorders (see, e.g. column 4 lines 44-53).

One of ordinary skill in the art of creating the claimed invention would have been motivated to modify Yoshioka's cosmetic composition's teachings to include the other claimed active ingredients as taught by Tanaka and Pola Chem Ind Inc. within Yoshioka's cosmetic compositions because the above combined references as a whole would create the claimed method of treating the skin by applying to the skin a composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent) to treat skin disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose..."

Art Unit: 1655

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product (i.e. L-arginine originated in a rice preparation and/or plant preparation) does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE  
PRIMARY EXAMINER